

# A multicomponent structured health behaviour intervention to improve physical activity in long-distance HGV drivers: the SHIFT cluster RCT

Stacy A Clemes,<sup>1,2\*</sup> Veronica Varela-Mato,<sup>1,2</sup>  
Danielle H Bodicoat,<sup>3</sup> Cassandra L Brookes,<sup>4</sup>  
Yu-Ling Chen,<sup>1,2</sup> Edward Cox,<sup>5</sup>  
Charlotte L Edwardson,<sup>2,6</sup> Laura J Gray,<sup>7</sup>  
Amber Guest,<sup>1</sup> Vicki Johnson,<sup>8</sup> Fehmidah Munir,<sup>1,2</sup>  
Nicola J Paine,<sup>1,2</sup> Gerry Richardson,<sup>5</sup>  
Katharina Ruetzger,<sup>1</sup> Mohsen Sayyah,<sup>1</sup>  
Aron Sherry,<sup>1,2</sup> Ana Suazo Di Paola,<sup>4</sup>  
Jacqui Troughton,<sup>8</sup> Simon Walker,<sup>5</sup>  
Thomas Yates<sup>2,6</sup> and James King<sup>1,2</sup>

<sup>1</sup>School of Sport, Exercise and Health Sciences, Loughborough University, Loughborough, UK

<sup>2</sup>National Institute for Health and Care Research Leicester Biomedical Research Centre, Leicester, UK

<sup>3</sup>Independent researcher, Leicester, UK

<sup>4</sup>Leicester Clinical Trials Unit, University of Leicester, Leicester, UK

<sup>5</sup>Centre for Health Economics, University of York, York, UK

<sup>6</sup>Diabetes Research Centre, University of Leicester, Leicester, UK

<sup>7</sup>Department of Health Sciences, University of Leicester, Leicester, UK

<sup>8</sup>Leicester Diabetes Centre, University Hospitals of Leicester NHS Trust, Leicester, UK

\*Corresponding author [S.A.Clemes@lboro.ac.uk](mailto:S.A.Clemes@lboro.ac.uk)

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**Disclaimer:** This report contains transcripts of interviews conducted in the course of the research, or similar, and contains language which may offend some readers.

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## Scientific summary

### SHIFT cluster RCT

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# Scientific summary

## Background

Owing to the nature of their occupation, long-distance heavy goods vehicle (HGV) drivers are exposed to a multitude of health-related risk factors and have been identified as working within one of the most hazardous professions. The working environment of long-distance HGV drivers and their job demands (e.g. long irregular hours, enforced sedentarism, poor dietary options, high stress) constrain the enactment of healthy behaviours, leaving drivers vulnerable to a myriad of physical and mental health conditions. Furthermore, long and variable working hours, including shift work, contribute to sleep deprivation, and this can lead to metabolic disturbances and further promote the uptake of unhealthy behavioural choices. As a result of their working environment and poor health behaviours, HGV drivers exhibit high rates of obesity and cardiometabolic risk factors. These factors likely culminate in HGV drivers having an increased risk of accidents, higher rates of chronic diseases and reduced life expectancies in comparison with other occupational groups. Despite this, HGV drivers are currently underserved in terms of health promotion efforts.

We developed the Structured Health Intervention For Truckers (SHIFT) programme, which is a multicomponent theory-driven health behaviour intervention designed to promote positive lifestyle changes in relation to physical activity, diet and sitting in HGV drivers. The SHIFT intervention has been informed by extensive public and patient involvement, which has included drivers and relevant stakeholders. Initial pilot testing of our intervention delivery suggested that it led to potentially favourable increases in physical activity, as well as increases in fruit and vegetable intake. The current study extends this work by evaluating the multicomponent SHIFT programme within a cluster randomised controlled trial (RCT), with the inclusion of full process and cost-effectiveness evaluations.

## Aim and objectives

The aim of this study was to evaluate the effectiveness and cost-effectiveness of the multicomponent SHIFT programme, compared with usual care, in a sample of long-distance HGV drivers at both 6 months and 16–18 months.

### Primary objective

- To investigate the impact of the 6-month SHIFT programme, compared with usual care, on device-measured physical activity (expressed as steps/day) at 6 months' follow-up.

### Secondary objectives

- To investigate the impact of the SHIFT programme, compared with usual care, at 6 months' follow-up on:
  - time spent in light physical activity and in moderate or vigorous physical activity (MVPA)
  - sitting time
  - measures of adiposity [i.e. body mass index (BMI), per cent body fat, waist–hip ratio, neck circumference]
  - cardiometabolic risk markers [i.e. glycated haemoglobin (HbA<sub>1c</sub>), total cholesterol, high-density lipoprotein cholesterol (HDL-C) and low-density lipoprotein cholesterol (LDL-C)]
  - fruit and vegetable intake and dietary quality

- blood pressure
  - psychophysiological reactivity
  - sleep duration and quality
  - functional fitness (i.e. grip strength)
  - cognitive function
  - mental well-being (i.e. anxiety and depression symptoms, and social isolation)
  - work-related psychosocial variables (i.e. work engagement, job performance and satisfaction, occupational fatigue, presenteeism, sickness absence and driving-related safety behaviour)
  - health-related quality of life (HRQoL)
  - health-related resource use (i.e. general practitioner visits).
- To investigate the longer-term impact of the SHIFT programme, compared with usual care, at 16–18 months' follow-up on:
    - steps per day
    - time spent in light physical activity and in MVPA
    - sitting time
    - fruit and vegetable intake and dietary quality
    - sleep
    - mental well-being (i.e. anxiety and depression symptoms, and social isolation)
    - work-related psychosocial variables (i.e. work engagement, job performance and satisfaction, occupational fatigue, presenteeism, sickness absence and driving-related safety behaviour)
    - HRQoL.
  - To conduct a mixed-methods process evaluation throughout the implementation of the intervention (using qualitative and quantitative measures) with participating drivers and site managers.
  - To undertake a full economic analysis of the SHIFT programme.

## Methods

### *Design and setting*

We conducted a two-armed cluster RCT, which incorporated an internal pilot phase and included mixed-methods process and economic evaluations. The trial took place within the worksite setting of a major international logistics and transport company [i.e. DHL Supply Chain (Milton Keynes, UK)]. DHL Supply Chain agreed to provide the setting and gave access to their drivers and sites for our research. Transport sites/depots formed individual clusters and were located across the Midlands region of the UK.

### *Participants*

All HGV drivers within participating sites were eligible to participate, unless they met any of our exclusion criteria. Drivers were excluded from the trial if they were suffering from clinically diagnosed cardiovascular disease, had mobility limitations that prevented them from increasing their daily activity levels, were suffering from haemophilia or any blood-borne virus, or were unable to provide written informed consent. Written informed consent was obtained from participants before baseline measurements and before each set of follow-up measurements.

### *Sample size*

To detect a difference in mean daily step counts of 1500 steps per day between the intervention and control groups [assuming a standard deviation (SD) of 2919 steps/day, 80% power, a two-tailed significance level of 5%, an intraclass correlation coefficient of 0.05, an average cluster size of 10 and a coefficient of variation to allow for variation in cluster size of 0.51], we required 110 participants from 11 clusters per arm. The sample size was inflated by 30% to account for loss to follow-up/non-compliance

to the activPAL™ (PAL Technologies Ltd, Glasgow, UK). In addition, the number of clusters was inflated by two to allow for whole-cluster drop out. Therefore, we aimed to recruit 24 clusters (transport sites) with an average of 14 participants per cluster, providing a total target sample size of 336 drivers. The internal pilot was conducted using the first six clusters (sites) recruited and examined issues surrounding worksite and participant recruitment, randomisation, compliance to the primary outcome and retention rates at 6 months' follow-up.

### **The SHIFT intervention**

The SHIFT programme is a multicomponent lifestyle-behaviour intervention that is designed to target behaviour changes in physical activity, diet and sitting in HGV drivers. The 6-month intervention, grounded within social cognitive theory for behaviour change, consists of a group-based (4–6 participants) 6-hour structured education session, tailored for HGV drivers and delivered by two trained educators. The education session was supplemented by health coach support (provided over a 6-month period) and equipment provision, including a Fitbit® (Fitbit Inc., San Francisco, CA, US) (to monitor daily step counts and set goals), resistance bands/balls and a hand gripper (to facilitate a 'cab workout'). Using the step count data recorded by the Fitbit, drivers were invited to participate in 6-weekly tailored step count challenges throughout the 6-month intervention.

### **The control arm**

Participants received an educational leaflet at the outset, detailing the importance of healthy lifestyle behaviours (i.e. undertaking regular physical activity, breaking up periods of prolonged sitting and consuming a healthy diet) for the promotion of health and well-being. Control participants completed the same study measurements as participants in the intervention worksites, at the same time points and received the same health feedback immediately following their measurements. Aside from receiving a generic health education leaflet and feedback from their measurements, the control group carried on with usual practice for the duration of the study.

### **Outcome measures**

Baseline measurements took place prior to randomisation of the sites into the two study arms (i.e. the SHIFT arm and the control arm). A second set of identical measurements took place at the 6-month follow-up. The measurements took place within the transport sites and were conducted by researchers who had undergone relevant training. A final set of measurements took place at the 16- to 18-month follow-up. The final follow-up measures were delayed because of the COVID-19 pandemic (the measures were initially planned for a 12-month follow-up) and consisted of predominantly self-report measures because of restrictions in face-to-face data collection. Owing to the pandemic, the primary outcome was also changed from assessment at 12 months to assessment at 6 months.

### **Primary outcome**

The primary outcome was device-measured physical activity, expressed as mean steps per day using the activPAL accelerometer, at 6 months' follow-up.

### **Secondary outcomes**

Secondary outcomes measured from the activPAL included time per day spent sitting, standing, stepping, in prolonged sitting bouts, in light intensity physical activity and in MVPA, and the number of sit-to-stand transitions. Variables were summarised for three different time periods within each measurement period: (1) daily (i.e. across all waking hours on all valid days), (2) workdays and (3) non-workdays. The GENEActiv (Activinsights, Kimbolton, UK) wrist-worn accelerometer was used to provide a measure of sleep duration and quality. The data from the accelerometer were summarised using the same time periods (i.e. daily, workdays, non-workdays) as were applied to the activPAL data. Data were collected on adiposity (i.e. BMI, fat percentage, waist circumference), and finger-prick blood samples were collected to measure HbA<sub>1c</sub>, cholesterol (i.e. HDL-C, LDL-C and total) and triglycerides. Fruit and vegetable intake and dietary quality were assessed using a Food Frequency Questionnaire. Blood pressure, cognitive function, psychophysiological reactivity and functional fitness (i.e. grip strength) were also assessed. Further self-report measures

collected at each assessment, via a questionnaire booklet, included mental well-being, musculoskeletal symptoms, occupational fatigue, job satisfaction and performance, work engagement, sickness absence, presenteeism, perceived work ability, job demands and control, and driving-related safety behaviour.

The primary analysis was performed using a mixed-effect linear regression model, using a complete-case population. Sensitivity analyses were conducted, including intention to treat, per protocol and the effect of a different number of valid activPAL days.

### **Economic evaluation**

Self-reported HRQoL and health-related resource use data were collected at each assessment point. The economic evaluation assessed the costs and outcomes associated with the SHIFT programme when compared with usual practice. The costs and outcomes were assessed over the time period of the trial and also over a longer time horizon to reflect the fact that short-term changes in activity are associated with longer-term improvements in health.

### **Process evaluation**

A mixed-methods process evaluation was conducted to examine intervention fidelity, dose, effectiveness of implementation strategies, potential contamination, barriers and sustainability. Participants completed feedback questionnaires 1 month after their baseline and 6-month assessments. In addition, following completion of the trial, focus groups and semistructured interviews took place with participants and managers.

## **Results**

### **Recruitment**

A total of 382 participants (mean  $\pm$  SD age: 48.4  $\pm$  9.4 years; BMI: 30.4 kg/m<sup>2</sup>  $\pm$  5.1 kg/m<sup>2</sup>; 99% male) were recruited across 25 clusters and randomised (at the cluster level) into either the SHIFT arm (12 clusters,  $n = 183$ ) or the control arm (13 clusters,  $n = 199$ ). An additional site was recruited because one internal pilot site had restrictions on when participants could wear the activPAL and GENEActiv accelerometers. The 25 transport sites operated within the transport, retail, hospitality, health-care, pharmaceutical, construction, oil and gas, and automotive industries, and the average age of our sample and our sex split match the average age of HGV drivers and the sex proportions seen nationally. Between baseline and 6-month follow-up, two sites (one intervention site and one control site) dropped out of the trial. For both sites, this was because of site closures due to the collapse of the contracting companies. At baseline, participants accumulated 8583 [interquartile range (IQR) 6922–10,696] steps per day and spent 11 hours (SD 95 minutes) per day sitting, 10 (IQR 6–19) minutes per day in MVPA and 99 (IQR 82–123) minutes per day in light physical activity. Forty-two per cent of the sample were classified as overweight, and 46% were classified as having obesity at baseline.

### **Primary outcome**

Valid accelerometer data were available from 209 (54.7%) participants for the primary outcome analysis. At 6 months, significant differences in mean daily steps were found between groups, with the SHIFT group accumulating 1008 (54.7%) more steps per day than the control group [95% confidence interval (CI) 145 to 1871 steps;  $p = 0.022$ ]. This difference was largely driven by the maintenance of physical activity levels in the SHIFT group and a decline in physical activity in the control group. Sensitivity analyses showed similar results to the primary analysis, with significant differences observed between groups when including participants with  $\geq 2$ , 3 and 4 valid days of activPAL data.

### **Secondary outcomes**

Favourable changes at 6 months were also seen in the SHIFT group, relative to the control group, in time spent sitting (–24 minutes/day, 95% CI –43 to –6 minutes/day), standing (14 minutes/day, 95% CI 2 to 26 minutes/day) and stepping (11 minutes/day, 95% CI 2 to 21 minutes/day), and time in

MVPA (6 minutes/day, 95% CI 0.3 to 11 minutes/day). These differences were largely driven by changes in behaviours on non-workdays. No differences between groups were observed when these variables were assessed at 16–18 months' follow-up. No differences were observed between groups in the other secondary outcomes at either follow-up (i.e. 6 months or 16–18 months).

### **Economic evaluation**

The average total cost of delivering the SHIFT programme was £369.57 per driver, and resulting quality-adjusted life-years were similar across trial arms (SHIFT arm: 1.22, 95% CI 1.19 to 1.25; control arm: 1.25, 95% CI 1.22 to 1.27). Analyses revealed that the probability of the SHIFT programme being cost-effective in the within-trial period was low, with a probability of between 0.009 and 0.011 for the range of cost-effectiveness thresholds considered. Overall, the SHIFT programme was associated with higher costs than usual practice, with little impact on other outcomes. Therefore, it was concluded that the SHIFT programme is not likely to be cost-effective in its current delivery format, and this result was robust to a range of alternative assumptions and additional analyses.

### **Process evaluation**

Questionnaire and interview data indicated favourable attitudes towards the SHIFT programme from both drivers and managers. The Fitbit was the most favoured component of the intervention, whereas the cab workout appeared to be the least favoured. The education session was deemed useful for facilitating improvements in knowledge and behaviour change; however, only dietary knowledge changes from the education session were predominantly recalled. Receiving feedback about their current health status from the physiological outcome measurements assessed at baseline and 6 months motivated participants to change aspects of their lifestyle (proportion agreeing: intervention, 91.1%; control, 67.5%). Barriers to a healthy lifestyle at work were still apparent and affected drivers throughout the study, with participants predominantly making positive behaviour changes on non-workdays.

## **Conclusions**

The SHIFT programme may have had a degree of success in positively affecting physical activity levels and reducing sitting time in HGV drivers at 6 months; however, these differences were not maintained at 16–18 months. Owing to the nature and demands of the occupation, the statistically significant differences observed between groups in these behaviours were largely driven by changes occurring on non-workdays, and largely attributable to the maintenance of physical activity levels in the SHIFT arm and a decline in physical activity levels in the control arm. The process evaluation revealed favourable attitudes towards the SHIFT programme from both drivers and managers, with drivers highlighting that the education session, Fitbit and step count challenges were particularly effective for facilitating behavioural changes. Managers and participants reported enthusiasm and a sense of necessity for the SHIFT programme to be included in future Certificate of Professional Competence training for professional drivers in the UK.

The high prevalence of drivers with obesity, along with the poor cardiometabolic health profile and sleep deprivation seen in our sample, highlight substantial health issues in this at-risk and hard-to-reach occupational group. Although the longer-term impact of the SHIFT programme is unclear, the programme (with refinement) has the potential to be incorporated into driver training courses to promote activity in this essential and underserved occupational group.

### **Trial registration**

This trial is registered as ISRCTN10483894.

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